

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

WRITTEN OPINION

(PCT Rule 66)

To: RICHARD L. CHINN  
BBLON SPIVAK MCCLELLAND MAIER &  
NEUSTADT  
CRYSTAL SQUARE FIVE, FOURTH FLOOR  
1755 JEFFERSON DAVIS HIGHWAY  
ARLINGTON, VA 22202

Date of Mailing  
(day/month/year)

23 JUL 2001

Applicant's or agent's file reference

196351W077

REPLY DUE

within TWO months  
from the above date of mailing

International application No.

PCT/US00/21970

International filing date (day/month/year)

14 SEPTEMBER 2000

Priority date (day/month/year)

14 SEPTEMBER 1999

International Patent Classification (IPC) or both national classification and IPC  
Please See Supplemental Sheet.

Applicant

CANFIELD WILLIAM M.

1. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step or industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

3. The applicant is hereby invited to reply to this opinion.

**When?** See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).~~

**How?** By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

**Also** For an additional opportunity to submit amendments, see Rule 66.4.  
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.  
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 14 JANUARY 2002

Name and mailing address of the IPEA/US  
Commissioner of Patents and Trademarks  
Box PCT  
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

TEKCHAND SAIDHA

Telephone No. (703) 308-0196

## I. Basis of the opinion

## 1. With regard to the elements of the international application: \*

☒ the international application as originally filed☒ the description:

pages 1-69, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of

☒ the claims:

pages 70-86, as originally filed  
pages NONE, as amended (together with any statement) under Article 19  
pages NONE, filed with the demand  
pages NONE, filed with the letter of

☒ the drawings:

pages 1-4, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of

☒ the sequence listing part of the description:

pages NONE, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of

## 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).  
☐ the language of publication of the international application (under Rule 48.3(b)).  
☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

- ☐ contained in the international application in printed form.  
☒ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority in written form.  
☐ furnished subsequently to this Authority in computer readable form.  
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.  
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

- ☒ the description, pages NONE  
☒ the claims, Nos. NONE  
☒ the drawings, sheets/fig NONE

5. ☐ This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed".

WRITTEN OPINION

International application No.

PCT/US00/21970

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. statement

Novelty (N)

Claims	<u>2-105</u>	YE
Claims	<u>1</u>	NO

Inventive Step (IS)

Claims	<u>2-105</u>	YE
Claims	<u>1</u>	NC

Industrial Applicability (IA)

Claims	<u>1-105</u>	YF
Claims	<u>NONE</u>	NC

2. citations and explanations

Claim 1 lacks novelty under PCT Article 33(2) as being anticipated by Bao et al. [JBC 271 (49) : 31437-31445, 1996]. Bao et al. teach a bovine GlcNAc-phosphotransferase and anticipates the claim.

Claims 2-105 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest the claimed specific amino acid and the nucleic acid sequences, vectors, host cells and the methods of making the diesterase, phospho-transferase, antibodies to the enzymes, and the methods of using the enzymes. Kornfeld et al. teach a multimeric structure of bovine N-acetylglucosamine-1-phosphodiester N-acetylglucosamine, however, the specific diesterase sequence claimed is outside the range of teachings of Kornfeld et al. Similarly, Bao et al. teach a bovine GlcNAc-phosphotransferase however, the specific phosphotransferase sequence claimed is outside the range of teachings of Bao et al.

Claims 1-105 have industrial applicability under PCT Article 33(4), because the subject matter claimed can be made or used in industry.

NEW CITATIONS

NONE

**VIII. Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claim 7 is objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because the claim is indefinite for the following reason(s): Claim 7, line 3 recites nucleotide 2949-3952 of SEQ ID NO : 6. The claim is indefinite because SEQ ID NO : 6 as per sequence search is an amino acid sequence and a nucleotide sequence.

**Supplemental Box:**

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

**TIME LIMIT:**

The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.

**CLASSIFICATION:**

The International Patent Classification (IPC) and/or the National classification are as listed below:

IPC(7): C12N 9/12, 9/14, 1/20, 15/00; C07H 21/04; A61K 38/44, 38/51; C07K 14/00 and US Cl.: 435/194, 195, 252.3, 320.1; 536/23.2; 424/94.5, 94.6; 530/387.1, 388.1